K063836

AUG 16 2007

5. 510(k) Summary

This summary of safety and effectiveness is submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

510(k) Owner and Manufacturing Site	Medtronic Neurosurgery 125 Cremona Drive Goleta, CA 93117 USA 805-968-1546 ext. 1773 805-968-9336 (FAX)
Establishment Number	2021898
Contact Name	Jeffrey Henderson
Date Summary Prepared	December 22, 2006
Trade or Proprietary Name	Medtronic Rivulet™ Ventricular Catheter Medtronic Rivulet™ Snap Shunt Ventricular Catheter Medtronic Rivulet™ Convertible Ventricular Catheter
Common Name	Hydrocephalus Shunt Component - Catheter
Classification Name	Central Nervous System Fluid Shunt and Components (21 CFR 882.5550, Product Code JXG)

Predicate Device Identification

- Medtronic PS Medical® Ventricular Catheter (K792007)
- Medtronic Ventriculostomy Reservoir (K874498)

Device Description

The Rivulet™ Ventricular Catheter is a proximal catheter used in the shunting of cerebrospinal fluid (CSF), allowing for the drainage of CSF from the ventricles of the brain. The Rivulet Catheter has varying sized, evenly spaced inlet flow holes located within 1.15 cm (0.45") of the tip of the catheter. The Rivulet Catheter is designed to equalize the distribution of inflowing CSF across all of the inlets holes as well as allow for intraventricular positioning of the inlet flow holes further away from the choroid plexus.

The Rivulet Catheter is available in two (2) shunt system connector styles: standard and snap shunt. The Rivulet Catheter with a standard connector measures 15 cm (5.9") in length, 0.15 cm (.06") in inner diameter, 0.25 cm (0.10") in outer diameter. The Rivulet Snap Shunt Catheters are available in lengths ranging from 4 cm (1.6") to 14 cm (5.5"). The Rivulet Catheters contain length markers to aid in determining depth of placement. To facilitate the placement and use of the Rivulet Catheters, procedural accessories supplied with the Rivulet Catheter include a stainless steel stylet, and a Right Angle Clip or Snap Base.

Indications for Use

The Rivulet Ventricular Catheter is designed for use as the proximal component of CSF Flow Control Shunts used in shunting cerebrospinal fluid from the ventricles of the brain to the peritoneal cavity or the right atrium of the heart.

Performance Characteristics

The Rivulet Catheter has similar technological characteristics to the currently marketed predicate devices listed above and conforms to the ISO 7197 Neurosurgical implants – Sterile single-use hydrocephalus shunts and components. The Medtronic PS Medical Ventricular Catheter was cleared in January 1980 (K792007) and allows for the drainage of CSF from the ventricles of the brain. CSF is taken into the inlet flow holes of these catheters via a pressure differential between the ventricles of the brain and the outlet of the corresponding shunt system. The Rivulet Catheters incorporate inlet flow hole configuration changes that allow the CSF to flow in a more equalized manner across all inlet holes and allows for intraventricular positioning of the inlet holes further away from the choroid plexus in normalized ventricles.

Technological Comparison

Medtronic Neurosurgery submits that the indications for use, function, implantation techniques, performance characteristics, design specifications, and test standards of the Rivulet Catheter are the same as the previously reviewed and cleared Ventricular Catheter and Ventriculostomy Reservoir. Based upon the summary above, Medtronic Neurosurgery determines substantial equivalence, safety, and efficacy of the Rivulet Catheter based upon the predicate and currently marketed devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Medtronic Neurosurgery
% Mr. Jeffrey Henderson
Vice President, Quality and Regulatory Affairs
125 Cremona Drive
Goleta, California 93117-5500

JAN 22 2013

Re: K063836
Trade/Device Name: Medtronic Rivulet™ Ventricular Catheter
Regulation Number: 21 CFR 882.5550
Regulation Name: Central nervous system fluid shunt and components
Regulatory Class: II
Product Code: JXG
Dated: July 19, 2007
Received: July 23, 2007

Dear Mr. Henderson:

This letter corrects our substantially equivalent letter of August 16, 2007.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure [ONLY NEED ENCLOSURE FOR 1996 FILES THAT HAVE INDICATIONS FOR USE STATEMENTS]

4. Indications for Use Statement

510(k) Number (if known): K063836

Device Name: Medtronic Rivulet™ Ventricular Catheter

Indications For Use:

The Rivulet™ Ventricular Catheter is designed for use as the proximal component of CSF Flow Control Shunts used in shunting cerebrospinal fluid from the ventricles of the brain to the peritoneal cavity or the right atrium of the heart.

Prescription Use ✓ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative,
and Neurological Devices

510(k) Number K063836